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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/620,331	07/20/2000	Kimberly R. Gamble	ML-02C	2749

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Kenneth S Watkins Jr
372 River Drive
Dahlonega, GA 30533

EXAMINER

QUAN, ELIZABETH S

ART UNIT	PAPER NUMBER
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1743

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DATE MAILED: 06/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/620,331

Applicant(s)

GAMBLE ET AL.

Examiner

Elizabeth Quan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 14-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 10-13 is/are rejected.
- 7) ☒ Claim(s) 10 and 12 is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 July 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II, claims 10-13 in Paper No. 4 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: (136) mentioned on page 8, line 22. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: (401) in FIG. 4, and (505) in FIG. 5. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to because the arrow in FIG. 2D could be labeled with a reference character or omitted since the specification does not mention it. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

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Specification

5. The disclosure is objected to because of the following informalities: On page 1, line 22 “procedures for” should be “procedures at.” On page 1, line 29 the term “evolutions” is incomprehensible within the given context. On page 2, line 6 “in” should be “into.” On page 3, line 19 “inert” should be “insert.” This error occurs throughout the specification. On page 3, line 24 “penetrateable” should be “penetrable.” This error occurs throughout the specification. On page 15, line 15 “body 103” should be either “body 101” or “chamber 103” although it is unclear how sample fluid is “surrounding the lower portion of body 101 or chamber 103.” On page 9, line 16 “though” should be “through.” On page 10, lines 21 and 22 there appears to be an omission between “aperture 215 and outer sample chamber 203” and “bottom end opening 221.” On page 10, line 28 “on” should be “in.” On page 11, line 24 “contaminates” should be “contaminants.” The error occurs throughout the specification. Appropriate correction is required. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

6. Claim 10 is objected to because of the following informalities: “a” should be inserted between “depositing” and “sample” in the last line of the claim. Appropriate correction is required.

7. Claim 12 is objected to because of the following informalities: “the” should be inserted between “transport” and “sample fluid” in the second to the last line of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 12 recites the limitation "penetrating sample deposit/extraction device" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim.

11. Claim 13 is rejected based on its dependency on claim 12.

12. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: inserting the insert into the sample well, positioning the sample deposit/extraction element over an opening on the septum seal, and inserting the sample deposit/extraction element through the septum seal. Otherwise, it would be unclear as to how the sample well is positioned with the sample deposit/extraction element through frictional engagement of the sample deposit/extraction element and the septum seal.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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14. Claims 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,567,309 to Classon et al.

Referring to claims 10 and 11, Classon et al. disclose a method of testing samples. A volume-adjusting insert (12), which comprises a septum seal (37) in the upper portion and seal surface (36,38,39) on the outer surface, is inserted into a sample well (100) (see FIGS. 4-7; COL. 7, lines 1, 2, and 41-44 and 57-67; COL. 8, lines 1-3 and 17-22). A through-chamber (67,68) is located between the septum seal (37) and bottom end of the insert (see FIGS. 4-7; COL. 7, lines 33-40). The seal surface (36,38,39) and through-chamber (67,68) defines a reduced-volume sample chamber as compared to the sample well (100) (see FIG. 7). A penetrating sample deposit/extraction element (86) is inserted through the septum seal (37) and deposits a sample fluid into the reduced-volume sample chamber (see FIGS. 4-7; COL. 8, lines 17-33). The sample well (100) is positioned with the sample deposit/extraction element (86) through frictional engagement of the sample deposit/extraction element (86) and the septum seal (37) (see FIGS. 4-7; COL. 7, lines 41-67; COL. 8, lines 1-25). Therefore, Classon et al. includes all the limitations of claims 10 and 11.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,567,309 to Classon et al. as applied to claims 10 and 11, and further in view of U.S. Patent No. 6,083, 761 to Kedar et al. and U.S. Patent No. 4,787,971 to Donald.

Referring to claims 12 and 13, Classon et al. disclose using hydraulic pressure generated by the penetrating sample deposit/extraction device (86) to transport the sample fluid through the through-chamber (67,68) (see FIGS. 4-7; Col. 8, lines 4-25). Furthermore, the sample fluid is passed through a processing element (24) (see FIGS. 4-7; COL. 17-38). Classon et al. do not disclose a sample well with a bottom-extraction opening. However, multi-well plates with wells having a hole at the bottom are well

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known accessory equipment for solid phase extraction and draining of wastes as provided in Kedar et al. and Donald. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the through-chamber of Classon et al. with the bottom extraction hole taught by both Kedar et al. and Donald to perform solid phase extraction and drain wastes from the through-chamber, as disclosed by Kedar et al. and Donald.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art includes one or more limitations of the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (703) 305-1947. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 879-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Elizabeth Quan
Examiner
Art Unit 1743

Maureen M. Wallenhorst
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